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Self-management education may improve blood pressure in people with type 2 diabetes. A randomized controlled clinical trial

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Abstract *Background and aims:* Diabetes is a suitable model to evaluate intervention programmes aimed at chronic diseases, because of its well-defined and measurable process and outcome indicators. In this study, we aimed at investigating the effects of group based self-management education on clinical and psychological variables in type 2 diabetes.
Methods and results: Four-year randomized controlled clinical trial (ISRCTN14558376) comparing Group Care and traditional one-to-one care. Clinical and psychological variables were monitored at baseline, 2 and 4 years. Although differences between groups appear to be non-significant at univariate analysis, body weight, BMI and HbA1c, systolic and diastolic blood pressure improved in the patients followed by Group Care but not among Controls. Prescription of lipid-lowering and anti-hypertensive agents did not change among the patients on Group Care, whereas anti-hypertensives were stepped up among Controls without improving their blood pressure. Multivariable analysis suggests that blood pressure improvement among patients on Group Care was independent of BMI, duration of diabetes and antihypertensive medication, suggesting a direct effect of education, presumably by increasing adherence. The "Powerful Others" dimension of the Locus of Control worsened and fear of complications decreased among Controls.
Conclusions: The results confirm that a multidisciplinary structured group educational approach improves blood pressure, presumably through better adherence to healthy lifestyle and medication, in people with type 2 diabetes.
Clinical trial registration number: ISRCTN14558376.

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Introduction

Chronic diseases represent a rising burden for the health of ageing populations and for expenditure related to medication, complications, hospital admissions and rehabilitation [1]. Hence, innovative strategies aimed at reducing costs while improving health outcomes are sorely needed.

Diabetes is a suitable model to evaluate intervention programmes aimed at chronic diseases, because of its well-defined and measurable process and outcome indicators [1]. The prevalence of type 2 diabetes (T2D), in particular, is on the rise worldwide because of unhealthy eating and sedentary lifestyles [2] while, on the other hand, only half the patients achieve recommended therapeutic targets for metabolic and blood pressure control [3]. T2D requires on the part of those affected continuous attention to lifestyle habits, adhesion to therapy, regular follow up visits and ability to interact with health care providers while not being overwhelmed by discouragement from the moment they receive the diagnosis [4]. Consequently, an integrated approach to patient-centered care will make sure that clinical decisions are taken with an eye to possible barriers to adherence, such as individual perception of illness, health literacy, cultural and religious beliefs [5,6].

Patient education, especially self-management education, is key to achieve the above goals. While traditional education defines the problems, self-management education allows patients to identify their problems and provides techniques to help them make decisions, take appropriate action and alter actions as circumstances or disease change [7,8]. Previous studies show how much the educational approach, its conceptual framework and the time dedicated to people are paramount in supporting change in health behaviours [9], metabolic control [10] and adherence to pharmacological treatment [11].

Within this context, we have validated a self-management model that, with adequate pedagogic approach, shifts the focus from the traditional organization of diabetes care delivery to group training and education activities that reallocate available resources in the clinic while ameliorating patients' health indicators [12]. Our Group Care model was reproducibly shown feasible and effective in daily practise and transferable to other settings, after adequate training of providers and engagement of all stakeholders [12,13]. The aim of this study was to investigate the effects on persons with T2D of participating in group based self-management education compared to individual education on clinical and psychological variables. On top of the effects on body weight, HbA1c and blood pressure, we applied a battery of psychometric tools to assess the Locus of Control, anxiety, depression and self-esteem because, in previous reports, these were tested only in post-hoc analyses [14,15] or a non-controlled follow up of patients with type 1 diabetes managed by Group Care [16].

Methods

Study population

This was a parallel, randomized controlled clinical trial (ISRCTN14558376) in which 50 people with T2D were recruited through digital medical records of 90 patients in our diabetes clinic and randomized to either Group Care ($n = 25$) or traditional one-to-one care ($n = 25$) for a predefined duration of 4 years (See CONSORT flow chart, Supplementary Fig. 1). The patients were aged <80, had at least 1-year previous attendance in our clinic and were treated by lifestyle either alone or associated with non-insulin anti-hyperglycaemic agents.

Our sample size had an 80% power to detect a difference of at least 12 mmHg decrease in systolic blood pressure in the treated group (Group Care) with respect to controls (standard care), with an alpha error <0.05. The calculation was based upon the observed mean of the control group at baseline (147 mmHg) and a common standard deviation in the two groups of 15 mm/Hg.

Ethics approval

The study had been approved by the Institutional Ethics Committees of Città della Salute e della Scienza di Torino and Ordine Mauriziano di Torino. All patients signed their informed consent to participate in the study, which conformed with the Declaration of Helsinki principles.

Patients

Recruitment began in June 2014, the trial started in January 2015 and was regularly completed in December 2018. Data on gender, age, duration of diabetes, schooling, living alone, occupation, smoking habits and anti-hyperglycaemic treatment are shown in Table 1 along with clinical data at baseline.

Body weight and body mass index (BMI), fasting blood glucose (glucose-oxidase), HbA1c (HPLC), systolic and diastolic blood pressure, changes in anti-hyperglycaemic, anti-hypertensive and lipid-lowering medication were monitored 4-monthly. Yearly screening for complications included serum creatinine, total and HDL cholesterol, triglyceride, microalbuminuria/creatininuria ratio and fundus examination. LDL Cholesterol was calculated according to Friedewald's formula (total − HDL cholesterol − triglyceride/5) [17]. eGFR was calculated according to the Cockroft-Gault formula [18]. Psychological assessment was done at baseline and after 2 and 4 years.

Blood pressure was measured by a physician (PF) after 5 min lying using a mercury sphygmomanometer. Fundus examination was by digital retinal photography according to Italian screening guidelines [19], following pupil dilatation by 1% tropicamide. Colour photographs of two 45° fields (centred on macula and nasal to disc) were graded

Table 1 Socio-demographical variables.

	Group care (n = 25)	Controls (n = 25)	Significance[a]
Sex	M = 16; F = 9	M = 16; F = 9	1.000
Age	62.1 ± 9.1	62.6 ± 7.5	0.883
Schooling[b]	3/13/6/3	7/9/6/3	0.526
Occupation (Retired/Active in work)	15/10	15/10	1.000
Social status (Living alone/Married)	5/20	5/20	1.000
Known duration of diabetes (years)	12.9 ± 5.2	9.6 ± 4.2	**0.016**
Attendance in clinic before study (years)	9.3 ± 4.1	7.0 ± 3.3	**0.008**
Family history of DM (No/Yes)	9/16	7/18	0.544
Smoking (Never/Currently/Stopped)	8/1/16	9/9/7	**0.007**
Anti-hyperglycaemic treatment: lifestyle only/anti-hyperglycaemic agents (AHA)	1/24	1/24	1.000

Bold means statistically significant.
[a] Chi-square test for categorical variables and t-test for continuous variables, or Wilcoxon rank-sum test.
[b] P = Primary school. M = Middle school. H = High school. U = University degree.

by an expert physician (MP) and DR classified as: absent (corresponding to ETDRS grade 10), mild (microaneurysms only or isolated blot haemorrhages) (ETDRS grade 20), moderate (ETDRS grade 35), severe non-proliferative (ETDRS grades 47–53), or proliferative (ETDRS grades >53) [20].

Anti-hyperglycaemic treatment was ranked both as class of medication (lifestyle alone, anti-hyperglycaemic agents) and number of agents prescribed (metformin, sulphonylureas, GLP-1 receptor agonists, DPP4 inhibitors, pioglitazone, SGLT2 inhibitors). Insulin, if introduced during the study, was accounted for as overall dosage. Changing from diet alone to anti-hyperglycaemic agents, adding insulin to the latter and/or switching to insulin alone ranked as one step up in medication.

Blood pressure medication was quantified as number of different classes of anti-hypertensive drugs prescribed, and lipid-active medication as prescription of statins and/or ezetimibe and/or fenofibrate, according to clinical judgement.

Randomization

The Statistical Unit of the Dept. of Public Health and Pediatrics carried out the subjects' allocation to either group. Allocation was based on a 0 (Control group)/1 (Group Care) sequence, with the first assignment randomly attributed to one of the two groups. The three sub-unities of the Group Care were composed on the basis of a randomly generated sequence of numbers (from 1 to 25) after assigning each subject a sequential number (from 1 to 25), based on the alphabetical order of their surnames. After composing three groups of 8 subjects, the 25th subject was randomly assigned to one of the three groups.

Group Care procedures

Twenty-five patients were randomized to Group Care and assigned to 3 groups of 8–9 patients each, reorganizing their booking schedules, while 25 controls continued with traditional individual consultations. All patients were followed in the diabetes clinic by the same physician (PF) for all aspects related to their clinical management.

The Group Care model to manage T2D was described previously [15,21]. The intervention involves a series of 7 sessions or modules held every 3–4 months and repeated twice over 4 years. Each module includes 3 phases: a) welcome, b) the main content or topic of the session, including role-playing with real life simulations, allowing patients to express their opinions and tell their life experience with diabetes, and c) a final phase of summing up and delivery of next appointment. Sessions last 60 min and are followed by individual consultations with the physician to comment on clinical results and selected aspects of the previous group session, address emerging problems, if any, and yearly visits to screen for complications.

Psychometric evaluation

Four questionnaires were administered at baseline and after 2 and 4 years to measure:

- anxiety and depression by the Hospital Anxiety e Depression Scale (HADS) [22], consisting of 14 items with two sub-scales. Scores of 11 or higher on either or both sub-scales indicate moderate-severe symptoms or a clinically significant disorder. Scores of 8–10 on either sub-scale indicate mild levels of anxiety or depression;
- diabetes-specific Locus of Control by the Peyrot and Rubin tool [23], including a set of 18 statements measuring expectancies of Internal, Chance, and "Powerful Others" control over diabetes-related health outcomes. The questionnaire consists of 6 items for each of 3 domains, measuring the degree to which subjects consider their diabetes to be under their own control, dependent on chance, or others. All items had identical response options (from "strongly disagree", scoring 1, to "strongly agree", scoring 6 on a 6-point Likert-like format) and none required reverse scoring;
- quality of life, using a DQOL/Mod version translated and revalidated into Italian [15,21] that includes 39 items. Answers are along a 5-point Likert scale, from 1 (very satisfied) to 5 (very dissatisfied). The Satisfaction

section includes 14 items and explores the patients' psychological well-being. The Impact dimension, 20 items, mostly assesses the practical consequences of diabetes on everyday life. Finally, the 5-item "Worry: Social-Vocational" Section investigates diabetes-related anxiety, with special reference to clinical conditions. The score ranges from 39 (best quality of life) to 195 (worst quality of life);

- self-esteem by the Rosenberg Self-Esteem Scale [24], widely used in social-science research, that includes 10 items to be answered on a four-point Likert scale, from "strongly agree" to "strongly disagree". The scales measure self-esteem by asking the respondents to reflect on their current feelings. The score ranges from 10 to 40, where higher scores correspond to better levels of self-esteem.

Statistical analysis

Analysis was by intention to treat. Data are shown as absolute frequencies for categorical data and mean ± SD for continuous variables.

Chi-square test for categorical variables and t-test for continuous variables, or Wilcoxon rank-sum test in case of nonparametric distribution, were carried out to assess whether significant differences between Group Care and Controls could be shown for socio-demographic data at baseline.

A t-test was then performed to compare the two groups with respect to the mean differences between 4 years and baseline for the clinical data taken into account in our study.

Differences between values at baseline and after 2 and 4 years for clinical data and for the scores of psychometric evaluation (anxiety and depression, locus of control, quality of life, self-esteem) were checked in both groups by paired t-test for continuous variables and Mc Nemar test for categorical variables, as appropriate.

Finally, differences between Group Care and controls at final evaluation were assessed by fitting multivariable models where, for both HbA1c and systolic blood pressure (SBP), the difference between final and baseline values were the dependent variables and treatment group (Group Care vs control group), known duration of diabetes, BMI differences (4 years-baseline), baseline value of the dependent variable and oral anti-hypertensive therapy at 4 years (for SBP model only) were taken as independent variables.

For all tests, a p-value of less than 5% was considered significant.

All analyses were performed with Stata 14 (StataCorp LLC, Texas, USA).

Results

The patients were mostly retired, only a minority lived alone and had a university degree. Despite randomization, those followed by Group Care had longer disease duration and attendance in clinic before study, and smoked less (Table 1). One of the patients randomized to Group Care died during the study but there were no other dropouts (Supplementary Fig. 1). In total, patients on Group Care attended 14 sessions over 4 years and controls were seen individually at regular intervals for the same total number of visits.

Univariate analysis showed no significant differences for nearly all clinical variables, when comparing the two groups for changes between 4 years and baseline (Tables 2 and 3), the only exceptions being fasting blood glucose and the Satisfaction dimension of the DQOL/Mod questionnaire.

On the other hand, within group analyses (Table 2) showed that, by year 4, patients followed by Group Care improved their body weight, BMI, HbA1c, systolic and diastolic blood pressure. BMI and HbA1c had improved already after the first 2 years (data not shown). There were trends to reduction in total and HDL cholesterol and triglyceride. None of the above changed significantly among the patients followed by traditional visits, except for transiently lower body weight, SBP and triglyceride levels at 2 years (data not shown), not sustained at the end of study. Serum creatinine increased, and eGRF declined, in both groups. The level of diabetic retinopathy did not change. Four patients in each group started insulin during the study. Lipid-lowering and anti-hypertensive agents did not change among the patients on Group Care, whereas antihypertensive therapy was stepped up among Controls (23 on medication at year 4 vs 17 at baseline, $p = 0.014$), without improving their blood pressure.

As regards psychological dimensions (Table 3) the Satisfaction dimension of the DQOL/Mod improved among the Controls. Within groups, at year 4, the "Powerful Others" dimension of the Locus of Control increased, and fear of complications decreased, among Controls. Non-consistent changes occurred among the patients followed by Group Care.

Multivariable analysis (Table 4) shows that, among the patients followed by Group Care, blood pressure had improved significantly, independently of BMI, known duration of diabetes and antihypertensive medication, suggesting a direct effect of Group Care. In contrast, the improvement of HbA1c in Group Care patients was not significantly different from controls after adjusting for known duration of diabetes and BMI variation. Also the Satisfaction dimension of the DQOL/Mod questionnaire did not show a statistically significant difference between the two groups after controlling for known duration of the disease (data not shown).

Discussion

This paper confirms previous reports that self-management education by Group Care has better effects than standard care on people with T2D [12,13], presumably by improving lifestyle as strongly suggested by the sustained 4-year drop in body weight and HbA1c. A novel observation in this trial is the drop in blood pressure, which we did not observe previously and, according to multivariable analysis, may have resulted not only from

Table 2 Clinical Variables at baseline and year 4 and comparisons between study groups.

	Group care			Controls			GC vs Controls Δ t4-t0
	Baseline (n = 25)	Four years (n = 24)	p[a]	Baseline (n = 25)	Four years (n = 25)	p[a]	p
Body weight (kg)	83.48 ± 11.60	79.46 ± 13.44	**0.0044**	77.50 ± 10.97	75.72 ± 11.41	0.0561	0.219
Body Mass Index (kg/m^2)	29.62 ± 3.38	28.05 ± 3.41	**0.0028**	28.2 ± 4.25	27.54 ± 4.24	0.0527	0.209
Fasting blood glucose (mg/dl)	159.84 ± 41.84	140.17 ± 35.42	0.0948	144.28 ± 49.1	159.12 ± 45.39	0.2140	**0.039**
HbA_{1c} (percent of total Hb)	7.63 ± 0.92	7.21 ± 0.94	**0.0294**	7.31 ± 0.78	7.39 ± 0.96	0.7600	0.115
$HbA1_c$ (mmol/mol)	59.92 ± 10.10	55.83 ± 11.89	**0.0417**	56.48 ± 8.43	57.36 ± 10.66	0.7612	0.107
Systolic blood pressure (mmHg)	141.28 ± 16.52	131.88 ± 15.17	**0.0167**	147.24 ± 16.34	145.76 ± 17.93	0.6921	0.194
Diastolic blood pressure (mmHg)	79.2 ± 9.92	73.96 ± 6.75	**0.0298**	78.76 ± 13.05	81.4 ± 13.85	0.4405	0.069
Total cholesterol (mg/dl)	176.2 ± 29.99	171.0 ± 33.71	0.6513	189.24 ± 29.36	185.84 ± 39.64	0.5983	0.991
HDL cholesterol (mg/dl)	54.08 ± 14.7	50.0 ± 13.39	**0.0494**	48.56 ± 9.23	49.40 ± 11.34	0.7130	0.117
LDL cholesterol (mg/dl)	97.0 ± 27.16	95.79 ± 30.45	0.9812	112.8 ± 29.72	109.08 ± 36.40	0.5417	0.674
Triglyceride (mg/dl)	125.72 ± 87.43	122.33 ± 68.61	0.9197	143.04 ± 42.67	135.48 ± 52.47	0.4468	0.794
Creatinine (mg/dl)	0.90 ± 0.20	0.96 ± 0.26	**0.0149**	0.86 ± 0.20	0.97 ± 0.27	0.0655	0.527
eGFR (ml/min)	98.67 ± 25.48	93.11 ± 24.77	**0.0334**	95.96 ± 26.16	87.43 ± 23.48	0.0877	0.725
ACR	2.88 ± 4.14	1.42 ± 2.23	0.0628	2.45 ± 3.27	2.87 ± 3.67	0.6561	0.114

Bold means statistically significant.
[a] Paired t-test for continuous variables.

decreased body weight but from a direct effect of the education program. Although drug assumption was not formally monitored, we suggest that Group Care, with its emphasis on lifestyle attitudes and importance of pharmacological medication, may have improved patient adherence to anti-hypertensive prescriptions, which remained unchanged throughout the trial. In contrast, control patients followed by traditional individual appointments and education, maintained stable metabolic control but worsened their blood pressure despite increased prescription of anti-hypertensive drugs. Similar findings were reported by Mühlhauser et al. [25] who studied patients with hypertension – not diabetes and hypertension – and over an 18 month follow up observed a drop from 162/100 to 154/95 mmHg in the active group vs 161/98 to 158/96 in the controls. The order of magnitude is the same as in this paper (from 141/79 to 132/74 among the active, and 147/79 to 146/81 among controls) which, considering the different therapeutic targets and drugs available in the early '90s, compares well. On the other hand, ours were office measurements and no special instructions were given to patients for home monitoring blood pressure. Unfortunately, these effects on metabolic and blood pressure control did not stop the decline in renal function in either treatment group. The rise in serum creatinine and corresponding drop in eGFR reached statistical significance in the Group Care group only, despite a trend to decreased urinary albumin/creatinine ratio and similar absolute values in both treatment groups. Lower data dispersion and longer duration of disease in the Group Care patients may have contributed to this result.

Other studies reported that adherence to medication improves when people with chronic diseases are led to believe in their own ability to control illness and develop

Table 3 Psychological assessment at baseline and year 4.

	Group care			Controls			GC vs Controls Δ t4-t0
	Baseline (n = 25)	Four years (n = 24)	p[a]	Baseline (n = 25)	Four years (n = 25)	p[a]	p
HADS_Depression	4.28 ± 3.34	4.5 ± 3.86	0.5348	4.24 ± 3.02	3.44 ± 2.95	0.2199	0.198
HADS_Anxiety	4.52 ± 3.14	4.83 ± 3.25	0.6146	5.24 ± 3.33	5.28 ± 3.45	0.9260	0.706
Locus Internal	30.16 ± 5.01	31.88 ± 4.17	0.0805	30.64 ± 3.97	30.96 ± 4.35	0.6870	0.232
Locus Chance	16.6 ± 6.9	17.54 ± 9.18	0.5466	18.76 ± 7.83	18.72 ± 7.26	0.9772	0.618
Locus Others	26.1 ± 5.03	27.42 ± 5.48	0.2352	24.2 ± 4.91	26.44 ± 5.45	**0.0491**	0.629
DQOL/Mod Total	68.2 ± 11.73	66.17 ± 10.49	0.2944	67.12 ± 12.4	63.2 ± 10.95	0.0600	0.431
DQOL/Mod Satisfaction	26.8 ± 5.79	27.63 ± 5.65	0.2679	30.92 ± 7.98	28.28 ± 6.86	0.0634	**0.031**
DQOL/Mod Impact	32.36 ± 7.06	30.46 ± 4.91	0.0768	27.76 ± 4.6	27.88 ± 4.59	0.8968	0.143
DQOL/Mod Complications	9.08 ± 2.78	8.04 ± 3.33	0.1377	8.44 ± 2.95	7.08 ± 2.94	**0.0179**	0.537
Self Esteem Scale	32.32 ± 3.97	32.54 ± 4.59	0.7032	32.32 ± 4.04	32.56 ± 3.86	0.7860	0.918

HADS = Hospital Anxiety e Depression Scale.
Locus of Control tool.
DQOL/Mod = Diabetes Quality of Life/Mod.
Bold means statistically significant.
[a] Paired t-test for continuous variables.

Table 4 Differences between study groups: results from multivariable models with difference between 4 years and baseline values of SBP and HbA_{1c} as dependent variables.

	Δ SBP[a]	*p-value*
Treatment Group		
Controls	Ref	–
Group Care	**−15.9**	**0.002**
Known duration of diabetes	**1.12**	**0.016**
Δ BMI (4 years vs baseline)[b]	0.71	0.536
Oral antihypertensive agents at 4 years		
No	Ref	–
Yes	−6.24	0.237
Systolic Blood Pressure at baseline	−0.58	0.000
	Δ HbA_{1c}[c]	*p-value*
Treatment Group		
Controls	Ref	–
Group Care	−0.31	0.284
Known duration of diabetes	0.03	0.335
Δ BMI (4 years vs baseline)[b]	0.12	0.114
HbA_{1c} at baseline	−0.64	0.000

Bold means statistically significant.
[a] Δ SBP = difference between 4 years and baseline values of Systolic Blood Pressure.
[b] Δ BMI = difference between 4 years and baseline values of BMI.
[c] Δ HbA_{1c} = difference between 4 years and baseline values of HbA_{1c}.

stronger confidence in treatment [5]. A recent review exploring health beliefs in people with hypertension emphasized the importance of assessing individual beliefs, in particular perceived barriers and self-efficacy, to incorporate them in the design of strategies to improve adherence to medication [26].

Traditional diabetes education aims at imparting disease-specific information about diet, exercise, medication and blood glucose monitoring skills in an approach in which it is professionals who decide what to teach [7,11]. However, providing information may help improve knowledge in patients but will not result in durable adherence to a therapeutic regime, whereas a learning process based upon the methodological principles of adult education should address motivational aspects and emotional regulation, acceptance of diabetes, coping strategies and narration of real life situations [27].

In Group Care, educational objectives are defined together with the patients, who are helped to identify and share their problems and successes with the other participants and encouraged to report on their personal experience. Peer education is used as a tool to compare and learn strategies to manage life with diabetes. The educational setting is characterized by continuity and allows each person, over time, to talk about her/himself by listening to what is said within the group, using the positive dynamics of sharing and dialogue with other people [26].

The only changes observed in the battery of psychological tests were a reduced fear of complications in the Quality of Life scores of both patients on Group Care and controls, and a barely significant increase in the dependence on Powerful Others in the Locus of Control of the latter (Table 3). In previous post-hoc analyses, we had reported lower fatalistic attitudes and stronger internality in the Locus of Control of patients with T2D followed by Group Care [14,15], and improved anxiety, depression and self-esteem in a non-controlled follow up of patients with type 1 diabetes, also managed by Group Care [16]. These results, while confuting our previous data, underline the necessity of subjecting partial observations to proper randomized controlled trials.

This study has weaknesses. It was not, and could not be, blinded because of the very nature of the intervention. This is a common pitfall of all RCTs of non-pharmacological interventions, which cannot conform to the rules of double-blind placebo-controlled studies. Another shortcoming is that measurement of blood pressure was by standard office procedures. Among the strengths are the completeness of follow-up and data collection, the minimal dropout rate and the fact that both intervention and control groups were cared for by the same team of operators with a long experience in educational pathways for adults with a chronic disease.

The results of this study confirm the importance of a multidisciplinary approach to encourage the transmission of useful messages that enable people with a chronic disease to make decisions in their own lives, understand the value of self-care, improve health indicators and not be overwhelmed by illness.

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Declaration of Competing Interest

None of the authors has any competing interests to declare.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.numecd.2020.06.023.

References

[1] 2008-2013 action plan for the global strategy for the prevention and control of non communicable disease. World Health Organization; 2008. p. 1–48.

[2] American Diabetes Association. Improving care and promoting health in populations: standards of medical care in diabetes 2020. Diabetes Care 2020;43(Supplement 1):S7–13.
[3] Casagrande SS, Fradkin JE, Saydah SH, Rust KF, Cowie CC. The prevalence of meeting A1C, blood pressure, and LDL goals among people with diabetes, 1988–2010. Diabetes Care 2013;36:2271–9.
[4] Fink A, Fach EM, Schröder SL. 'Learning to shape life'. A qualitative study on the challenges posed by a diagnosis of diabetes mellitus type 2. Int J Equity Health 2019;18:19.
[5] Shahin W, Kennedy GA, Stupans I. The impact of personal and cultural beliefs on medication adherence of patients with chronic illnesses: a systematic review. Patient Prefer Adherence 2019;13: 1019–35.
[6] Mogre V, Johnson NA, Tzelepis F, Paul C. Barriers to diabetic self-care: a qualitative study of patients' and healthcare providers' perspectives. J Clin Nurs 2019;28:2296–308.
[7] Bodenheimer T, Lorig K, Holman H, Grumbach K. Patient self-management of chronic disease in primary care. JAMA 2002;288: 2469–75.
[8] Trento M. The utopia of research. Epistemology of patient education. Acta Diabetol 2019;56:145–50.
[9] Powers MA, Bardsley J, Cypress M, Duker P, Funnell MM, Fischl AH, et al. Diabetes self-management education and support in type 2 diabetes. Diabetes Educ 2017;43:40–53.
[10] Charvala CA, Sherr D, Lipman RD. Diabetes self-management education for adults with type 2 diabetes mellitus: a systematic review of the effect on glycemic control. Patient Educ Couns 2016; 99:926–43.
[11] Vermeire E, Hearnshaw H, Van Royen P, Denekens J. Patient adherence to treatment: three decades of research: a comprehensive review. J Clin Pharm Ther 2011;26:331–42.
[12] Trento M, Gamba S, Gentile L, Grassi G, Miselli V, Morone G, et al. For the ROMEO investigators. Romeo: rethink organization to improve education and outcomes. A multicentre randomised trial of lifestyle intervention by group care to manage type 2 diabetes. Diabetes Care 2010;33:745–7.
[13] Trento M, Passera P, Bajardi M, Tomalino M, Grassi G, Borgo E, et al. Lifestyle intervention by group care prevents deterioration of Type II diabetes: a 4-year randomized controlled clinical trial. Diabetologia 2002;45:1231–9.
[14] Trento M, Basile M, Borgo E, Grassi G, Scuntero P, Trinetta A, et al. A randomised controlled clinical trial of nurse-, dietitian- and pedagogist-led Group Care for the management of type 2 diabetes. J Endocrinol Invest 2008;31:1038–42.
[15] Trento M, Passera P, Miselli V, Bajardi M, Borgo E, Tomelini M, et al. Evaluation of the locus of control in patients with type 2 diabetes after long-term management by group care. Diabetes Metab 2006; 32:77–81.
[16] Trento M, Merlo S, Durando O, Rapetti S, Cavallo F, Porta M. Self-management education and psychological support improve self-esteem in people with type 1 diabetes. Acta Diabetol 2017;54: 415–6.
[17] Friedewald WT, Levy RI, Fredrickson DS. Estimation of the concentration of low-density lipoprotein cholesterol in plasma, without use of the preparative ultracentrifuge. Clin Chem 1972;18: 499–502.
[18] Cockroft DW, Gault MH. Prediction of creatinine clearance from serum creatinine. Nephron 1976;16:31–41.
[19] A.A.V.V. Linee Guida per lo Screening, diagnostica e il trattamento della Retinopatia Diabetica in Italia. Il Diabete 2016;28:190–231.
[20] Early Treatment of Diabetic Retinopathy Study Research Group. Early photocoagulation for diabetic retinopathy. ETDRS Report N.9. Ophthalmology 1991;98:766–85.
[21] Trento M, Passera P, Tomalino M, Bajardi M, Pomero F, Allione A, et al. Group visits improve metabolic control in type 2 diabetes. A 2-year follow-up. Diabetes Care 2001;24:995–1000.
[22] Zigmond AS, Snaith RP. The Hospital Anxiety e depression Scale. Acta Psychiatr Scand 1983;67:361–70.
[23] Peyrot M, Rubin RR. Structure and correlates of diabetes-specific locus of control. Diabetes Care 1994;17:994–1001.
[24] Prezza M, Trombaccia A. La scala dell'autostima di Rosenberg: traduzione e validazione italiana. Bollettino di Psicologia Applicata 1997;223:35–44.
[25] Mühlhauser I, Sawicki PT, Didjurgeit U, Jörgens V, Trampisch HJ, Berger M. Evaluation of a structured treatment and teaching programme on hypertension in general practice. Clin Exp Hypertens 1993;15:125–42.
[26] Al-Noumani H, Wu JR, Barksdale D, Sherwood G, AlKhasawneh E, Knafl G. Health beliefs and medication adherence in patients with hypertension: a systematic review of quantitative studies. Patient Educ Couns 2019;102:1045–56.
[27] Sanchez LM, Cooknell LE. The Power of 3: using adult learning principles to facilitate patient education. Nursing 2017;47:17–9.